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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/925,664

08/09/2001

Dan W. Denney JR.

GENTIOPE-06499

3389

23535

7590

02/23/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,664

Applicant(s)

DENNEY, DAN W.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Re: Denney D
Priority Date: 9 August 2001

1. The amendment filed 11/18/2004 is acknowledged and entered into the record. Accordingly, claims 1-20 and 27-32 are canceled without prejudice or disclaimer.
2. Claims 21-26 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 21-26 as failing to comply with the enablement requirement under 35 USC § 35 USC 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the claims of the instant invention are fully enabled because questions of efficacy are outside the realm of the Office. Moreover, applicant contends that the examiner is requesting evidence of safety in the treatment of human subject. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Contrary to what applicant has stated, the *prima facie* case of lack of enablement was made in a field that is considered highly unpredictable, namely the treatment of cancer. In the instant case, the claims are drawn to the administration of a multivalent composition for the purpose of active idiotype immunotherapy against B-cell lymphoma. The references cited are illustrative examples taken from the field of cancer immunotherapy and indicate that the field in general is unpredictable and underscore the importance of providing one of skill in the

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art with some reasonable aspect of guidance. Such guidance can be provided in the form of working examples that indicate to one of skill in the art that at the time of filing, the method instantly claimed when administered would in fact perform the function of active idiotype immunotherapy against B-cell lymphoma as claimed. Thus, absent such disclosure, one of skill in the art given the relatively unpredictable nature of cancer and treatments of cancer would be forced into undue experimentation to practice the instant invention. For example, the specification on pages 88-103 provide a working example for the construction of a multivalent vaccine against B-cell lymphoma, the administration of the multivalent vaccine, and propose methods of monitoring the effects of the vaccine, however, the specification fails to provide one of skill in the art that the administration of the multivalent vaccine is able to generate an active immunotherapeutic regimen against B-cell lymphoma as claimed. Thus, the specification essentially, provides a plan or an invitation for those of skill in the art to experiment in order to practice the claimed invention but does not provide sufficient guidance or specificity as to how to execute that plan. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement in that will enable any person skilled in the art to make and use the invention.

Applicant additionally argues that the rejection is based on two assertions, 1) the unreliability of in vitro studies of anticancer agents, and 2) the unpredictability of antibodies for the treatment of cancer. Applicant contends that these arguments are irrelevant to the instant case because the instant invention is not based on the

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screening or administration of "unknown chemical compounds", or in the elicitation "passive immunotherapy." Instead, applicant contends that the instant invention is drawn to the administration of a multivalent composition and elicitation of active immunotherapy. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As stated above, the cited references are relied upon to show the general unpredictability of treating cancer. Applicant has not provided any evidence or exemplification that the method of administering a multivalent composition would be capable of inducing a passive immunotherapeutic response as claimed.

Thus given the relatively incomplete understanding in the field of cancer and the lack of a reasonable correlation between the narrow disclosure in the specification and broad scope of protection sought in the claims; the lack of enablement is deemed appropriate. See MPEP 2164.08. Therefore the rejection under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 11/18/2004.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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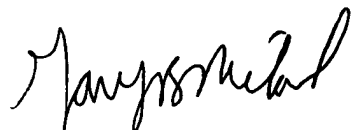
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
February 9, 2005



GARY NICKOL
PRIMARY EXAMINER